



August 3, 1999

Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, SW (HFS-450)  
Washington, DC 20204

8/3/99  
15/6/99

RE: Ricola® Herbal Health™ Immune Formula

To Whom It May Concern:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Ricola, Inc. ("Ricola"), Morris Plains, New Jersey 07950, hereby notifies the Food and Drug Administration that within the past 30 days the Company has begun marketing a dietary supplement with a label that bears statements of nutritional support. Ricola is the distributor of this product.

The dietary supplement for which the statements are made is Ricola® Herbal Health™ Immune Formula. Per serving size of one tablet, the supplement contains: Echinacea purpurea standardized extract, 100 mg; Astragalus root standardized extract, 100 mg; Panax ginseng root standardized extract, 100 mg; Elderberry juice concentrate, 50 mg; Bio-enhancing herbal blend, 12.5 mg (extracts of hyssop, lemon balm leaf, peppermint leaf, sage leaf and thyme leaf); Vitamin C, 250 mg; and Zinc, 10 mg.

The statements of nutritional support for this product read as follows:

- Ricola® Herbal Health™ Immune Formula is the natural way to help support healthy immunity.
- Enriched with vitamin C, zinc and standardized echinacea, this unique herbal formula features the traditional adaptogens Panax ginseng and astragalus. Adaptogens are special herbs used traditionally to balance and normalize the body's systems and to protect against stress at the cellular level.
- Immune Formula is further enhanced by a special blend of healthful Ricola herbs.

A copy of the outer package and inner-container label for the product is attached.

These statements are accompanied by the required disclaimer indicating that the statements have not been evaluated by FDA and that the product is not intended to diagnose, treat, cure or prevent any disease.

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Ricola USA, Inc.  
51 Gibraltar Drive  
Morris Plains, NJ 07950  
Phone: 973-984-6811 ■ 800-323-9073  
Fax: 973-984-6814  
E-mail: info@ricolausa.com

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Ricola certifies that it possesses adequate substantiation for these statements of nutritional support; that the substantiation renders them truthful and non-misleading and thus permissible under the DSHEA; and that the information contained in this notice is complete and accurate.

Sincerely,

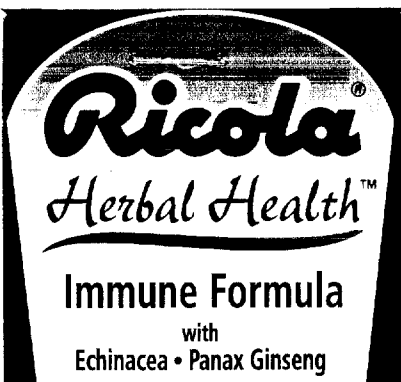
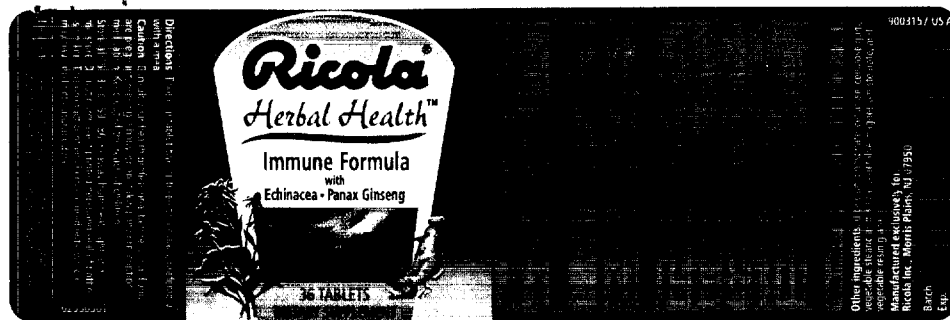
A handwritten signature in black ink, appearing to read "Dan Thomas", with a long, sweeping horizontal stroke extending to the right.

Dan Thomas  
President

Enclosure

Original plus two copies enclosed

# Ricola® Herbal Health™ Immune Formula



For more than sixty years the world has trusted the Ricola name for herbal products of the highest quality and purity. Today, the tradition continues with Ricola® Herbal Health™ supplements. Meticulously crafted by Swiss experts, these balanced formulas skillfully combine research-recommended levels of highly standardized botanicals with essential vitamins and minerals. Each formula is further enhanced for optimum digestibility with an exclusive blend of healthful Ricola herbs.

Ricola® Herbal Health™ dietary supplements also available:

- Active Memory Formula
- Heart Formula
- Antioxidant Formula
- Prostate Formula
- Women's Formula
- Mood Formula
- Night Time Formula

Other ingredients: dicalcium phosphate, cellulose, cellulose gum, vegetable stearic acid, silica, vegetable magnesium stearate, and vegetable resin oleate.

Exclusively manufactured for:  
Ricola Inc., Morris Plains, NJ 07950

For comments or questions on Ricola herbal supplements, call 1-800-323-9073, or visit us at [www.ricolausa.com](http://www.ricolausa.com).

Directions: Take one tablet two or three times daily, preferably with a meal.

Caution: Consult your health professional before using if you are pregnant, nursing a baby, or are taking any prescription medication. Keep out of the reach of children.

Store at 15–30°C (59–86°F) away from heat, light and moisture. Do not purchase if printed neckband seal of bottle is broken. This product contains herbal ingredients, which may have distinct natural odors.

Ricola® Herbal Health™ Immune Formula is the natural way to help support healthy immunity. Enriched with vitamin C, zinc and standardized echinacea, this unique herbal formula features the traditional adaptogens Panax ginseng and astragalus. Adaptogens are special herbs used traditionally to balance and normalize the body's systems and to protect against stress at the cellular level. Immune Formula is further enhanced by a special blend of healthful Ricola herbs.

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